

Meeting Minutes

DEPARTMENT OF HEALTH BOARD OF PHARMACY STERILE COMPOUNDING COMMITTEE

**October 18, 2016
Embassy Suites Lake Buena Vista South
4955 Kyngs Heath Rd
Kissimmee, FL 34746**

Committee Members:

Michele Weizer, PharmD, BCPS, Chair
Mark Mikhael, PharmD
Debra Glass, BPharm

Board Counsel:

David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Board Staff:

Allison Dudley, Executive Director
Bianca Bell, Program Operations Administrator
Alexandra Meredith, Regulatory Supervisor

Committee Chair, Michele Weizer called the meeting to order immediately following the Rules Committee.

1. Update from FDA Intergovernmental Meeting on Sterile Compounding

Discussion: Mr. Flynn provided update on the meeting in September for the two-day meeting. It was a working meeting with breakout sessions. The regulatory environment and FDA policies and procedures reviewed. Facilities 503a and 503b are going to continue to be inspected. The meeting discussed the switch from 797 compliance to 499 provision for unadulterated drug. The facility 503a needs to have a patient prescription before it is even prepared and is not for office use compounding. The facility 503b is for office use compounding. The meeting

discussed the federal government role versus state role in governing facilities. CGMP will no longer be a standard that is held if all exemption requirements are met. Ms. Dudley advised that a great deal of states are not currently working with outsourcing facilities. Virginia is the only other state currently working with these facilities. Mr. Flynn advised that there is a clear need for regulation of animal compounding, but vet meds were not touched on that much during the meeting. Dr. Weizer inquired if the one mile radius was addressed. Ms. Dudley advised that there was a statement made advising that this needs to be addressed as there have been many questions on this.

2. Rules Update

a. Rule 64B16-27.797, the Standards of Practice for Compounding Sterile Products

b. Rule 64B16-28.802, Special Sterile Compounding Permits

Discussion: This rule discusses the standards of practice for compounding sterile products. The adding the language under the proposed amendment for the ISO class 7 tiling was discussed. The language has been formally proposed and published and waiting the 21 day period for both of the above. The application will need to be worked on in the future for 28.802 permit. The 797 questions need to be removed from the application as they have to submit CGMP inspection. Mr. Flynn and Dr. Weizer will work on the application for the permit to incorporate the necessary changes.

3. Rule 64B16-28.905, Nonresident Sterile Compounding Permit Inspections; Approved Inspection Entities

a. Discussion re Inspection Entities for Outsourcing Facilities

Discussion: A discussion surrounding inspection entities for outsourcing facilities takes place which was legislatively stated, and Dr. Weizer inquires how to put this

legislation into rule. Mr. Flynn advised the board has been able to review whether or not inspections of these facilities are passing the CGMP inspections done by these entities. Mr. Flynn makes note that this renewal period will be the first that the board is involved in with regards to reviewing inspections and renewing these licenses. Dr. Mikhael advised how other states are ensuring that inspectors are able to conduct CGMP inspections by making inspectors go through yearly training to ensure that the inspectors are properly vetted. Ms. Dudley and Dr. Weizer discuss having inspectors with lengthy experience that complete these inspections. Dr. Mikhael advised of the costs of having these inspections completed when contracting out versus using our own inspectors. Dr. Weizer advised to wait to see how renewal period goes with the volume before starting to make standards.

4. USP 731 – Loss on Drying

Discussion: Dr. Weizer advised that this came as a clarification from Eric Castagno. Dr. Weizer advised of the loss on drying deals with non-sterile products. Dr. Weizer inquiring as to whether or not this needs to be opened for development. Mr. Flynn advised that he will need to look into rulemaking on the 797 and 795. Dr. Weizer discussed that if this is completed, 731 could possibility be removed. Rich Montgomery stepped up to confirm that USP 800 development was pushed to 2020 as Dr. Mikhael had stated.

5. FDA Guidance Documents (Informational)

No Discussion

6. Future meetings

Discussion: Dr. Weizer advised that the board will need to separate rules and sterile compounding committees into two separate days. Dr. Weizer is hoping to

start in December to place one on Monday afternoon and the other on the second day to leave more room for being productive.

7. New business/old business

No Discussion

8. Public Comment

Participants in this public meeting should be aware that these proceedings are being recorded.

No Discussion

Motion: by: Dr. Mikhael, to adjourn. Motion carried.

Meeting adjourned at 5:01 pm.